Citation:

Ledikwe JH, Rolls BJ, Smiciklas-Wright H, Mitchell DC, Ard JD, Champagne C, Karanja N, Lin PH, Stevens VJ, Appel LJ. Reductions in dietary energy density are associated with weight loss in overweight and obese participants in the PREMIER trial. *Am J Clin Nutr*. 2007 May; 85 (5): 1,212-1,221.

PubMed ID: 17490955

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To examine the effects of dietary and behavioral interventions on dietary energy density values and explore how six-month energy density changes relate to changes in anthropometric, dietary and health-related measures.

Inclusion Criteria:

- Generally healthy adults with above-normal blood pressure
- Prehypertension and stage 1 hypertension guidelines set in the 7th report of the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure
- Systolic blood pressure (SBP) of 120-159mmHg, diastolic blood pressure (DBP) of 80-95mmHg, or both, as determined from the mean blood pressure across three screening visits and if they were not taking anti-hypertensive medication
- Age >25 years
- BMI 18.5-40.0kg/m^2.

Exclusion Criteria:

- Regular use of drugs that affect blood pressure
- JNC-7 risk category C (target organ damage, diabetes or both)
- Use of weight-loss medications
- Prior cardiovascular event, heart failure, angina, cancer diagnosis or treatment in the past two years
- Consumption of >21 alcoholic drinks per week
- Pregnancy, planned pregnancy or lactation
- Participants who reported consuming <500kcal per day at either baseline or six months were excluded from the analyses.

Description of Study Protocol:

Recruitment

Targeted recruitment methods were used to ensure adequate representation of clinically important subgroups, such as African Americans.

Design

Randomized Clinical Trial.

Dietary Intake/Dietary Assessment Methodology

- Two unannounced, non-consecutive 24-hour dietary recalls collected by telephone on one weekend and one weekday; dietary data were collected using multiple-pass technique and portion size estimation aids
- Energy density values calculated only on the basis of food intake, excluding all beverages.

Blinding Used

Staff members were unaware of randomization assignment.

Intervention

Subjects randomized to one of three groups:

- Established group received an 18-session face-to-face intervention over six months (14 group meetings and four individual counseling sessions) implementing well-established hypertension recommendations (weight loss, sodium reduction and physical activity)
- Established plus DASH (Dietary Approaches to Stop Hypertension) group received the 18-session intervention also implementing the DASH diet
- Advice group received one 30-minute individual educational session on these topics at the time of randomization.

Statistical Analysis

- Analyses were conducted to compare participants by PREMIER treatment group
- Comparisons were also made after classifying participants on the basis of the magnitude of change observed in dietary energy density values over a period of six months by using tertile cutoffs
- Chi-square tests and ANOVA were used for categorical and continuous independent variables, respectively
- Baseline measures of independent variables were included as covariates
- Post hoc tests using a Tukey-Kramer adjustment for multiple comparisons were conducted only after establishing that the overall F statistic for the ANOVA model was significant
- Stepwise regression analyses were performed to determine which dietary changes were most predictive of changes in energy density and body weight.

Data Collection Summary:

Timing of Measurements

Analyses presented are based on overweight and obese subjects with dietary and anthropometric data at baseline and six months.

Dependent Variables

- Intake of energy, nutrients and food groups was assessed from two unannounced, non-consecutive 24-hour dietary recalls collected by telephone on one weekend and one weekday; dietary data were collected using multiple-pass technique and portion size estimation aids
- Energy density values calculated only on the basis of food intake, excluding all beverages
- Weight, height and waist circumference were measured by using calibrated scales, wall-mounted stadiometers and anthropometric measuring tape
- Physical activity assessed through seven-day physical activity recall.

Independent Variables

- Established group
- Established plus DASH group
- Advice group.

Control Variables

None.

Description of Actual Data Sample:

- *Initial N:* 810 were enrolled in the trial
- *Attrition (final N):* 658 subjects (81% of randomly assigned subjects), 61% women
- *Mean age:* 50±0.3 years
- *Ethnicity:*
    - 35% African American
    - 64% White
    - 1% Other
- *Other relevant demographics:* None.
- *Anthropometrics:* Baseline characteristics did not differ significantly between treatment groups. There were no significant (NS) differences between the participants according to group assignment for age, anthropometric measures, sex, race, education level or income
- *Location*: United States. Participating institutions included:
    - The National Heart, Lung and Blood Institute Project Office (Bethesda, MA)
    - The Coordinating Center (Kaiser Permanente Center for Health Research, Portland, OR)
    - Four clinical centers
        - Duke University Medical Center, Durham, NC
        - Johns Hopkins University, Baltimore, MD
        - Pennington Biomedical Research Center, Baton Rouge, LA
        - Kaiser Permanente Center for Health Research, Portland, OR).

Summary of Results:

Six-month Change by PREMIER Trial Treatment Group

Variables	Advice Group (N=223)	Established Group (N=219)	Established + DASH Group (N-216)
Change in Body Weight (kg)	-1.1±0.2[a]	-5.1±0.4[b]	-6.1±0.4[b]
Change in Waist Circumference (cm)	-1.3±0.4[a]	-5.3±0.4[b]	-5.3±0.4[b]
Change in BMI (kg/m^2)	-0.5±0.1[a]	-1.8±0.1[b]	-2.2±0.1[b]
Change in energy density (kcal per g food)	-0.17±0.03[a]	-0.26±0.04[a]	-0.56±0.03[b]
Change in total energy (kcal)	-173±43[a]	-321±37[b]	-286±40[b]
Change in food energy (kcal)	-137±40[a]	-257±35[b]	-263±38[b]
Change in beverage energy (kcal)	-36±13[a]	-64±12[b]	-24±14[a]
Change in food weight (g)	20±24[a]	8±20[a]	254±27[b]

[a,b] Values in the same row with different superscript letters are significantly different, P<0.05.

Other Findings

- Participants had a mean dietary energy density of 1.78±0.02kcal per gram at baseline
- Each group had significant declines in energy intake, dietary energy density and body weight (all P<0.001)
- The Established and Established plus DASH groups had the greatest body weight reductions (5.1kg and 6.1kg, respectively) compared to the Advice group (1.1kg)
- A similar pattern was seen for changes in waist circumference and BMI
- The Established and DASH group had the greatest dietary energy density reduction and the greatest increase in the weight of food consumed
- Regarding declines in dietary energy density, there was a decline of 0.17kcal per gram in the Advice group, 0.26kcal per gram in the Established group and 0.56kcal per gram in the Established and DASH group
- Weight loss for all participants at six months was significantly correlated with lower food energy density (r=0.28, P<0.001)
- When groups were combined and analyzed by dietary energy density change tertiles, participants in the highest tertile (largest dietary energy density reduction) lost more weight (5.9kg) than did those in the middle (4.0kg) or lowest (2.4kg) tertile
- Participants in the highest and middle tertiles increased the weight of food they consumed (300 and 80g per day, respectively), but decreased their energy intake (500 and 250kcal per day)
- Conversely, those in the lowest tertile decreased the weight of food consumed (100g per day), with little change in energy intake
- The highest and middle tertiles had favorable changes in fruit, vegetable, vitamin and mineral intakes.

Author Conclusion:

- In summary, achievement of considerable weight loss was related to reductions in the energy density of the diet. Participants with diet patterns characterized by the largest decrease in the energy density had the greatest decrease in energy intakes and the largest declines in body weight. Even modest reductions in energy density that accompanied increased intakes of fruit, vegetables, fiber, vitamins and minerals and of the total weight of food consumed were associated with reduced body weight
- These data indicate that a reduction in dietary energy density (even a modest reduction) is a healthy weight-management strategy. Eating patterns that are low in energy density, such as the DASH diet, can help to improve the efficacy of dietary interventions in the prevention and treatment of obesity.

Reviewer Comments:

Energy density values were calculated only on the basis of food intake, excluding all beverages. However, authors note that prior research indicated that including beverages in calculations of dietary energy density values may diminish associations with outcome variables, because of increased within-person variance.

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes

1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A

5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes

7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**	Yes
8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	Yes
8.6.	Was clinical significance as well as statistical significance reported?	Yes
8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**	Yes
9.1.	Is there a discussion of findings?	Yes
9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**	Yes
10.1.	Were sources of funding and investigators' affiliations described?	Yes
10.2.	Was the study free from apparent conflict of interest?	Yes